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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/804,895 | 03/19/2004 | Madhavan Pisharodi | PISA,015 | 8181 |
| 7590 | 11/19/2007 | | | |
| Mark Wisner c/o Wisner & Associates Suite 400 1177 West Loop South Houston, TX 77027 | | | EXAMINER PREBILIC, PAUL B | |
| | | | ART UNIT 3774 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/804,895

Applicant(s)

PISHARODI, MADHAVAN

Examiner

Paul B. Prebilic

Art Unit

3774

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 11 and 19-35 is/are pending in the application.
- 4a) Of the above claim(s) 1, 3 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 19-35 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Election/Restrictions

Claims 1, 3, and 11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on February 27, 2006.

Claim Objections

Claims 2, 19 and 29-35 are objected to because of the following informalities:

With regard to claim 2, on line 7, it is unclear how a portion of the implant can be biased away from "the implant" as claimed. Rather, a portion of the implant is biased away from "another portion" of the implant. The Examiner suggests making this change to make the claim language clearer.

With regard to claims 19 and 32-35, the step of "resisting" is confusing since this is not a manipulative step but rather, a feature provided by the implant structure.

With regard to claims 29-31, the steps of "maintaining" and "biasing" are confusing because there are not manipulative steps, but rather, features provided by the implant structure.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 19 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Perren et al (US 6,019,793). Perren anticipates the claim language where the inserting step as claimed is met by the inserting step of Perren (see column 3, line 66 to column 4, line 2 and see column 1, line 55 to column 2, line 12), the insert as claimed is one of either the upper plate (1) or lower plate (1), and the biasing step as claimed is done by means (4) of Perren. The upper plate (1) or lower plate (2) is movably mounted relative to the rest of the implant in that the means (4) allows relative movement.

With regard to claim 24, the springs as claimed are met by the connecting means (4) of Perren.

Claims 2, 28, 29, and 31-35 are rejected under 35 U.S.C. 102(b) as being anticipated by Sertich (US 5,800,550). Sertich anticipates the claim language where the implant as claimed is met by implant body (148) and the insert as claimed is met by peg (190); see Figures 8 and 9, column 8, lines 18-24, column 9, line 53 to column 10, line 14 and column 2, lines 36-48.

With regard to claim 29, the material of the peg is considered compressible because no material is perfectly rigid and would inherently be capable of providing cushioning depending upon how it was situated in the body.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19-21, 24, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al (US 6,669,731) or Ralph et al (US 5,989,291) in view of Muhanna (US 6,936,070). Ralph ('291) meets the claim language where the inserting step as claimed is disclosed by Ralph '291 on column 5, lines 49-65, the implant is upper plate (102a or 103a), the insert as claimed is the lower plate (102b or 103b), the biasing is done by the Belleville washer (130 or 230) and the step thereof is disclosed on column 2, lines 43-55, and the restraining step as claimed is disclosed by Ralph on column 2, lines 56-65. Alternatively, Ralph ('731) meets the claim language where the implant as claimed is the plate (102b) (see Figure 5), the insert as claimed is the plate (102a), and the biasing is done by the washer (130) (see Figure 5, column 2, line 52 to column 3, line 68, and column 6, lines 31-53) Both Ralph '291 and '731 fail to disclose the step of removing a portion of the intervertebral disk as claimed. However, Muhanna teaches that removal of the intervertebral disk prior to implantation of Ralph ('291) was clearly known to the art; see column 2, lines 9-22. Therefore, it is the Examiner's position that it would have been clearly obvious, if not required for operability, to remove at least a portion of the intervertebral disk in either the Ralph('731) or Ralph ('291) method to make room for the implant that replaces the structure and function of the defective disk.

With regard to claims 20-21, Muhanna teaches that it was known to fill a space around a similar implant with collagen gel, which is a type of hydrogel; see column 7, lines 3-19. Therefore, it is the Examiner's position that it would have been obvious to an ordinary artisan to fill any space around either of the Ralph implants with collagen gel

for the same reasons that Muhanna does the same or to aid in the cushioning effect desired.

With regard to claim 21, collagen gel is considered to be a protein polymer or a collagen matrix to the extent that this language can be given patentable weight.

Claims 22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ralph et al ('731), Ralph et al ('291), and Muhanna as applied to claims 19-21, 24 and 26 above, and further in view of Haldimann (US 6,428,576). Ralph ('731) or Ralph ('291) fail to disclose the use of an adhesive in the implantation method to contact the remaining disk or to seal an opening as claimed. However, Haldimann teaches that it was known to use medical grade adhesives to contact the disk and to seal openings; see Figure 1 and column 4, lines 27-48. Therefore, it is the Examiner's position that it would have been obvious to use the medical grade adhesive of Haldimann to contact the disk and to seal any openings in order to prevent migration of the implant or further herniation of the disk or for the same reasons that Haldimann utilizes the same.

Claim 30 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sertich (US 5,800,550) in view of Pisharodi (US 5,123,926). Sertich meets the claim language as explained *supra* but does not disclose compressing and releasing the insert as claimed. However, Pisharodi teaches that it was known to make similar implants with compressible/ releasable pegs; see Figure 4 and column 3, line 32 et seq. Therefore, it is the Examiner's position that it would have been obvious to utilize compressible and releasable pegs in the Sertich device for the same reasons that Pisharodi utilizes the same in that it would be a simple substitution of one peg type for another.

Response to Arguments

Applicant's arguments filed September 10, 2007 have been fully considered but they are not persuasive.

The Applicant argues that neither Perren or Ralph ('291 or '731) discloses an insert biased away from the implant as claimed; see page 8, last full paragraph of the response. However, the Examiner asserts that the claim language is fully met and that the plates (as inserts) are clearly biased away from the rest of the structure (the other plates). To interpret the claims more narrowly would be an error on the Examiner's part.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure

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outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action if the application is not stored in image format (i.e. the IFW system) or published.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Paul B. Prebilic whose telephone number is (571) 272-4758. He can normally be reached on 6:30-5:00 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Paul Prebilic/
Paul Prebilic
Primary Examiner
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